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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/943,286 08/30/2001 Kiyotada Nunomura GP104-03.CN1 8507 21365 7590 11/13/2002 GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121 ART UNIT PAPER NUMBER 1637 DATE MAILED: 11/13/2002					
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Examiner Teress E Strzelecka 1637 Period for Reply AS HORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM. THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM. THE MAILING DATE OF THIS COMMUNICATION. Electricate or time may be seriedle used the provision of 37 CPR 1.136(s). In no event, towever, may a reply be kinely filed the period for reply supplied above is less than thirty (30) days, a reply whith the stabilities witnimum of the (30) days will be considered threly. If No period for reply supplied above is less than thirty (30) days, a reply whith the stabilities witnimum of the (30) days will be considered threly. If No period for reply supplied above is less than thirty (30) days, a reply whith the stabilities witnimum of the (30) days will be considered threly. If No period for reply a supplied above is less than thirty (30) days, a reply whith the stabilities witnimum of the (30) days will be considered threly. If No period for reply a supplied above is less than thirty (30) days, a reply whith the stabilities witnimum of the (30) days will be considered threly. If No period for reply a supplied above is less than thirty (30) days, a reply whith the stabilities witnimum of the supplied above is less than the supplied of the supplied above is less than the supplied above	•	Application No.	Applicant(s)			
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THE MAILING DATE OF THIS COMMUNICATION. Extensions of the map to available under the provisions of 3° CFR 1.13(g), in no event, however, may a riply be timely filed after SIX (8) MCNTHS from the maining date of this communication. It no part of the real provision of the communication and the provision of the communication and the provision of the communication. It no part of or reply is spacification above, the maximum statutory period which be statutory minimum of thiny (8) days will be considered finely. It no part of or reply is spacification to be communication. The provision of the communication of the provision of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). See the attached details of the priority documents have been received in this National Stage app		ears on the cover sheet with the c	orrespondence address			
2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-55 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 7) Claim(s) is/are subjected to. 8) Claim(s) is/are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawings correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received in Application No. paper application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121. Attachment(s)	 THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 					
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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-28, drawn to a method for quantifying analyte polynucleotide in a sample,
 classified in class 435, subclass 91.1.
 - II. Claims 29-40, drawn to a method for relating pre-amplification amounts of analyte polynucleotide and post-amplification amounts of analyte amplicon, classified in class 435, subclass 6.
 - III. Claims 41-49, drawn to a method of determining whether a biological sample contains an analyte polynucleotide, classified in class 435, subclass 6.
 - IV. Claim 50, drawn to a method for determining whether an analyte polynucleotide is present in a test sample in an amount greater or less than a pre-determined value, classified in class 435, subclass 6.
 - V. Claims 51-55, drawn to a kit for performing amplification reaction, classified in class435, subclass 975.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.
- 3. Inventions V and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

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claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Groups I-IV can be practiced with an entirely different product, such as TaqMan probes and primers.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

November 11, 2002

KENNETH R. HORLICK, PH.D.

11/12/02